The specification has been amended to provide the missing information, namely, the additional identifying information for the related applications.

Response to Office Action Paragraphs 3-4 Claim Rejection Under Double Patenting

In the Office Action the Examiner provisionally rejected Claims 52-60 under the judicially created doctrine of obviousness-type double, over the copending Application No. 09/783,254 (although the Office Action referred to USPA Serial No., 09/782,804, Applicants believe that USPA Serial No. 09/783,254 was the intended application).

Applicants respectfully acknowledge this rejection and will address this rejection once the claims are otherwise in condition for allowance.

Response to Office Action Paragraphs 5-7 Claim Rejection Under 35 U.S.C. §102(b)

In the Office Action the Examiner rejected Claims 60 and 38-51 under 35 U.S.C. §102(b) as being anticipated by Domb et al. (USPN 5,512,055), and Claims 37, 52-54 and 57-59 as being anticipated by Gregory et al. (USPN 5,283,257).

In rejecting Claims 60 and 38-51, the Examiner stated that "Domb et al. disclose a stent with polymeric coatings with methylprednisolone as is claimed", referencing the abstract and column 5 lines 34-36 and column 6 lines 37-59.

Domb et al. is directed to devices for use in the naso-oto-pharyngeal areas and having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device. Among some embodiments, Domb et al. recites stoma stents and laryngeal/bronchial stents. Domb et al. names methylprednisolone, among a list of other compounds, which may be incorporated into the device.

The method of the present invention as claimed is directed to "a method for inhibiting restenosis in a blood vessel following recanalization of the blood vessel" by "implanting a vascular prosthesis in the blood vessel" and "releasing methylprednisolone

from the prosthesis into the blood vessel so as to inhibit smooth muscle cell proliferation."

Stoma stents are used to maintain the patency of a tracheostoma and are employed in maintenance of long-term or permanent tracheostomy in treatment of sleep apnea, bilateral vocal cord paralysis, laryngeal (glottic) insufficiency or stenosis due to trauma, carcinoma, radiation therapy, edema and other diseases; short-term tracheostomy when assisted respiration is not required; and following removal of cannula or T-Tube until adequate airway is assured or as an alternative to a T-Tube in appropriate cases.

In contrast to the present invention, Domb et al. provides no teaching whatsoever as to the release of methylprednisolone from a vascular (e.g. pertaining to blood vessels or indicative of a copious blood supply) stent to inhibit restenosis. It enables neither releasing methylprednisolone from a vascular stent in a blood vessel nor the inhibition of restenosis following recanalization. Domb et al. focuses on the use of stents for use in naso-oto-pharyngeal areas (which is not a blood vessel) to prevent stenosis resulting from the use of the stent itself.

"But to be prior art under section 102(b), a reference must be enabling. . . . That is, it must put the claimed invention in the hand of one skilled in the art." In re Sun, 31 USPQ 2d 1451, 1453 (Fed. Cir. 1993) (unpublished)

It further appears that the Examiner is basing the rejection on the idea that because methylprednisolone was mentioned as a possible anti-inflammatory drug for inhibiting inflammation in the naso-oto-pharyngeal areas which may result from the use of the device itself, it then anticipates the invention as claimed in the present application.

"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." W.L. Gore & Associates v. Garlock, Inc., 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

Applicants respectfully disagree with the Examiner that Domb et al. teaches the present invention as claimed in Claim 60 and submit that submit that Claim

60 and those depending directly or indirectly therefrom, are not anticipated by or obvious in view of Domb et al. and that they are patently distinguishable over the same.

Applicants respectfully request withdrawal of this rejection and the allowance of Claim 60, and all those depending directly or indirectly therefrom.

In rejecting Claims 37, 52-59, and 57-59, the Examiner noted that Gregory et al. disclose a method for treating hyperproliferative vascular disease by administering MPA (mycophenolic acid), and mizoribine (referencing the abstract and column 3 lines 44-52 and column 4 lines 24-31).

In contrast to the present invention, Gregory et al. does not teach or suggest the release of methylprednisolone from a vascular stent.

"Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic & Research Found. v. Genentech Inc., 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991)

Applicants submit that Claims 37, 52-59, and 57-59, are not anticipated by or obvious in view of Gregory et al., and that they are patently distinguishable over the same.

Applicants respectfully request withdrawal of this rejection and the allowance of Claims 37, 52-59, and 57-59.

Response to Office Action Paragraph 10 Allowable Subject Matter

Applicants note with appreciation the indication that Claims 55 and 56 will be allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims.

By way of present amendment, Claims 55 and 56 each has been rewritten in independent form in include all limitation of their respective base claims and are thus in condition for allowance.

Additionally, Applicants have added new Claim 61 depending from the allowable Claim 55.

Applicants respectfully request the allowance of newly amended Claims 55, 56, and 61.

CONCLUSION

Attached hereto is a marked-up version of the changes made to the claims by the present amendment, with pages captioned "**Version with markings to show changes made**." Additionally, a clean and complete version of all the pending claims as of present amended, captioned "**Clean Version With All Pending Claims**" has been also attached for Examiner's convenience.

The Applicants believe that the pending claims are directed to patentable subject matter. Consideration and an early allowance thereof are earnestly solicited.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Please amend the full paragraph starting on page 3 lines 18-21 as follows:

The disclosure of this application is related to the disclosures of the following applications being filed on the same day: 09/783,253 (Attorney Docket No. 20460-000910); 09/9,782,927 (Attorney Docket No. 20460-000920); and 09/783,254 (Attorney Docket No. 20460-000930).

IN THE CLAIMS

Please amend Claims 55 and 56; and add new Claim 61; as indicated below:

55. (Amended) A method **[as in claim 53]** for inhibiting restenosis in a blood vessel following recanalization of the blood vessel, said method comprising:

implanting a vascular prosthesis in the blood vessel; and

releasing methylprednisolone and at least one other substance in addition to methylprednisolone from the prosthesis when implanted in the blood vessel, wherein the immunosuppressive substance is mizoribine.

56. (Amended) A method **[as in claim 52]**for inhibiting restenosis in a blood vessel following recanalization of the blood vessel, said method comprising:

implanting a vascular prosthesis in the blood vessel; and

releasing methylprednisolone and at least one other substance in addition to methylprednisolone from the prosthesis when implanted in the blood vessel, wherein methylprednisolone is released within a time period of 2 days to 3 months.

61. (New) A method as in claim 55, wherein methylprednisolone is released within a time period of 2 days to 3 months and mizoribine is released within a time period of 1 day to 45 days.